K 123475

FEB - 3 2014

Section 5: 510k) Summary

The Summary of Safety and Effectiveness information on the Shoocin™ Introducer Kit is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant: **Telephone:**	Lepu Medical Technology (Beijing) Co., Ltd. No. 37 Chaoqian Road Changping District, Beijing 102200 P.R. China +86-10-80120641
Contact:	Shan Zhao
Date:	November 6, 2012
Name:	Shoocin™ Introducer Kit
Classification Name:	Catheter Introducer, 870.1340
Product Code:	DYB
Predicate:	Pinnacle Precision Access System, Terumo Corporation, K111606 with market clearance dates of October 3, 2011.
Description:	The Shoocin™ Introducer Kit consists of a puncture needle, a guide wire with a guide wire collimator, a sheath introducer, and a dilator. The puncture needle incorporates a lumen, which provides a conduit for the insertion of the guide wire into the vascular system. The flexible stainless steel guide wire is utilized as a guiding mechanism for the insertion of the introduction sheath into the vascular system. The guide wire contains a wire collimator, which assists in funneling the wire through the lumen of the puncture needle and contains marking that are visible under fluoroscopy, which can determine in length of the guide wire within the vascular system. The sheath introducer provides a conduit for introducing other interventional devices, including guide wires and interventional catheters, into the vascular system. The main components of this assembly are a non-hydrophilic coated sheath introducer, hemostasis valve housing, and a side port with tubing connected to a 3-way stopcock/valve. The dilator is used to provide support and stability to the sheath introducer during deployment into the vascular system. The proximal end of the dilator includes a luer port and has a tapered, atraumatic distal tip. Both the sheath and dilator contain bismuth, making these devices visible under fluoroscopy.
Intended Use:	The Shoocin™ Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

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Specification Comparison:

The Shoocin™ Introducer Kit specifications are similar to the Pinnacle Access System (K111606) and the differences do not raise any new issues of safety or effectiveness.

	Pinnacle	Shoocin
Sheath Diameter:	4F through 11F	4F through 11F
Sheath Length:	10cm – 25cm	7cm – 23cm
Guide Wire Length:	45cm	45cm and 80 cm
Guide Wire OD:	.035" - .038"	.018" - .038"
Introducer Needle:	19 – 21G	18 – 20G
Dilator:	15.5cm or 16.0cm	7cm, 11cm, 16cm, 23cm

Materials Comparison:

The Shoocin™ Introducer Kit materials have been subjected to biocompatibility tests and the differences between the Pinnacle Access System (K111606) do not raise any new issues of safety or effectiveness.

	Pinnacle	Shoocin
Needle:	Stainless Steel	Stainless Steel
Needle Luer:	Styrene-Butadiene	Polycarbonate
Guide Wire:	Stainless Steel or Nitinol w/Palladium distal coil	Stainless Steel
Guide Wire Collimator:	Polypropylene	Polycarbonate
Dilator Tube:	Polypropylene w/Bismuth subcarbonate	Polypropylene
Dilator Luer:	Polypropylene	Acrylobutyistyrene
Outer Sheath:	ETFE w15% BiO3, w/2% TiO2	Fluorinated Ethylene Propylene
Sheath base:	Styrene elastomer	Acrylobutyistyrene
Side Port Tubing	Polybutadiene	Polyurethane
Hemostasis Valve:	Silicone Rubber	Silicone
3-Way Stop Cock: Cap: Valve:	Polypropylene Polypropylene Polypropylene	Acrylobutyistyrene Polyethylene Polyethylene

Sterilization:

The method used is based on practices recommended by AAMI / ANSI / ISO 11135:2007 and provides a Sterility Assurance Level (SAL) of 10^{-6}

Shelf Life:

In accordance with ISO 11070 the real time aging of Shoocin™ Introducer Kit demonstrated that the performance of the specific components met the standard requirements without any significant difference to product performance requirements before aging. So the product is stable and reliable within the two-year useful life.

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Biocompatibility:

The Shoocin ™ Introducer Kit produced by Lepu Medical was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The Shoocin ™ Introducer Kit would be classified as an External Communicating Device in contact with the Circulating Blood for a Limited Duration (<24 hours). The following test would be required for any patient / user contacting material:

Test	Standard	Results
Haemolytsis	ISO 10993-4	Both the test article in direct contact with blood and the test article extract were non-hemolytic.
Cytotoxicity	ISO 10993-5	The test article extract showed no evidence of causing cell lysis or toxicity
Maximum Sensitization	ISO 10993-10	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Intracutaneous Irritation	ISO 10993-10	The test article met the requirements for the SC and SO test extracts.
Systemic Toxicity	ISO 10993-11	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.
USP Pyrogen Study	ISO 10993-11	The test article was judged as nonpyrogenic.
In Vivo Thromboresistance	ISO 10993-4	The test article and control were thromboresistant and comparable.
Partial Thromboplastin Time	ISO 10993-4	The test article would be considered a minimal activator and met the requirements of the test.

Performance Testing:

The Shoocin ™ Introducer Kit successfully passed all of the following performance tests:

Shoocin ™ Introducer Kit Performance Testing	
Sheath Introducer	Sheath Introducer should be free of defects
	Sheath Introducer ID
	Sheath Introducer Effective Length
	Radiodetectability
	Dilator accessibility
	Fracture Strength Test
	Leaking Performance Test

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Performance Testing: The Shoocin ™ Introducer Kit successfully passed all of the following performance tests:

Shoocin ™ Introducer Kit Performance Testing	
Dilator	Dilator should be free of defects
	Dilator OD
	Dilator ID
	Dilator Effective Length
	Radiodetectability
	Guide wire accessibility
	Fracture Strength Test
Guide wire	Surface free from impurity
	Guide wire length
	Guide wire OD
	Radiodetectability
	Corrosion Resistance
	Fracture Strength Test
	Flexing Resistance Test
	Associative Guide Wire Strength Test
Puncture Needle	Surface free from defects
	Needle OD
	Needle ID
	Needle Effective Length
	Accessibility – Guide wire
	Corrosion Resistance
	Joint Strength – Needle to hub

Substantial Equivalency Information: The information provided in this submission, comparing intended use, principle of operation and performance, the Shoocin™ Introducer Kit device is substantially equivalent to existing legally marketed device.

Conclusion: The information provided in this submission and comparing intended use, principle of operation and overall technological characteristics (i.e. puncture needle, guide wire, dilator, and sheath introducer to obtain access to the vascular system), the Shoocin™ Introducer Kit supports a determination of substantially equivalent to existing legally marketed predicate device Pinnacle Precision Access System. Any technological differences between the Shoocin™ Introducer Kit and the predicate Pinnacle Precision Access System device do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2014

Lepu Medical Technology (Beijing) Co., Ltd.
c/o Arthur Goddard
FDA Regulatory and Quality Systems Consultant
1531 Felton Road
South Euclid, Ohio 44121-2722

Re: K123475
Trade Name: Shoocin™ Introducer Kit
Dated: January 21, 2014
Received: January 27, 2014

Dear Mr. Goddard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K123475

Device Name: Shoocin™ Introducer Kit

Indications For Use:

The Shoocin™ Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

Prescription Use ___X___ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)